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COMPRESSIVE DEVICE FOR PERCUTANEOUS TREATMENT OF OBESITY

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[0001] The benefit of the filing date of provisional application Serial No. 60/494,698, filed 13 August 2003 is claimed under 35 U.S.C. § 119(e).

TECHNICAL FIELD

[0002] This invention pertains to multiple expandable devices that can be implanted to treat obesity in mammals by reducing the volume of the stomach.

BACKGROUND ART

[0003] Obesity is a complex, medical disease affecting more than 30% of the population in the United States. Obesity affects an individual's personal quality of life and contributes significantly to morbidity and mortality. Obese patients, i.e. individuals having a body mass index ("BMI") greater than 30, often have a high risk of associated health problems (e.g., diabetes, hypertension, and respiratory insufficiency), including early death. In the United States, approximately 280,000 deaths annually are attributed to obesity and obesity-related diseases. In the case of morbid obesity, studies have shown that conservative treatment with diet and exercise may be ineffective for reducing excess body weight. In addition, specific diets, medications, behavioral modifications, and exercise programs have over a 95% failure rate in morbidly obese individuals. Consequently, surgery is often the most effective means of treatment. "Bariatric surgery" is the field of surgery that treats people who are so overweight that they are suffering health consequences due to the excess weight. The surgery usually involves operations on the

stomach to restrict one's ability to eat, or on the small intestine to restrict the absorption of ingested food. *See* M. Deitel, "Overview of Obesity Surgery," *World J. Surg.*, vol. 22, pp. 913-918 (1998).

[0004] A successful bariatric surgery results in a maintained weight loss of greater than 50% of excess body weight and in an increase in patient wellness. An important factor for success is a long-term relationship between the patient and a medical team, which includes the doctor performing the procedure, a dietitian, a psychologist, and a physical therapist. While current bariatric surgery may assist patients in reducing food intake, it may also increase medical risks due to complications inherently associated with surgery, including complications of anesthesia, surgical procedure, wound infections, dehiscence, stomal stenosis, marginal ulcers, thrombophlebitis, and pulmonary problems.

[0005] There are several bariatric surgical procedures for treating morbid obesity. One procedure for treating morbid obesity is referred to as a "biliopancreatic diversion." Biliopancreatic diversion surgery is a reduction of the stomach volume and a diversion of food from the stomach to the final segment of the small intestine, bypassing the beginning and middle portions of the small intestine to limit the amount of nutrients and calories absorbed by the body. This procedure removes about one half of the stomach, and then connects the stomach to the last 250 cm of the small intestine. Disadvantages of this surgery include patients suffering from protein malnutrition, anemia, gastric retention, diarrhea, abdominal bloating, and intestinal obstruction. *See* P. Marceau, *et al.*, "Malabsorptive Obesity Surgery," *Surg. Clinics of North America*, vol. 81(5), pp. 1113-28 (2001).

[0006] Another bariatric surgery, "gastric bypass," is a bypass connecting the lower compartment of the stomach to the initial portion of the small intestine. This procedure limits the amount of food that can be ingested at one sitting and reduces absorption of food across the small intestine. In addition to surgical complications, patients may also suffer from acute gastric dilation, anastomotic leak, anemia, and dumping syndrome. *See* R.E. Brolin, "Gastric Bypass," *Surg. Clinics of North America*, vol. 81(5), pp. 1077-1096 (2001).

[0007] A third bariatric surgical procedure is "gastric banding," which constricts the stomach to form an hourglass shape. This procedure restricts the amount of food that passes from one section to the next, which induces a feeling of satiety. A band is placed around the

stomach near the junction of the stomach and esophagus. The small upper stomach pouch is filled quickly, and slowly empties through the narrow outlet to produce a feeling of satiety. In addition to surgical complications, patients undergoing this procedure may also suffer from esophageal injury, splenic injury, band slippage, staple line disruption, reservoir deflation/leak, and persistent vomiting. *See* E.J. DeMaria, "Laparoscopic Adjustable Silicone Gastric Banding," *Surg. Clinics of North America*," vol. 81(5), pp. 1129-44 (2001).

[0008] A fourth bariatric surgical procedure is "vertical-banded gastroplasty," which restricts the volume of the stomach by using staples. In this procedure, staples are placed in the upper stomach region to create a small pouch with a narrow outlet to the remaining portion of the stomach. A lap-band is placed around the narrow outlet to provide support and inhibit stretching of the stomach. In addition to surgical complications, patients undergoing this procedure may suffer from vomiting, ulcers, band erosion, and leaks. *See* C. Doherty, "Vertical Banded Gastroplasty," *Surg. Clinics of North America*, vol. 81(5), pp. 1097-1112 (2001).

[0009] U.S. Pat. No. 6,102,922 describes a device and surgical method for reducing the food intake of a patient by forming a restriction in the stomach using a band. In one embodiment, the band is looped around the esophagus and a portion of the stomach is pulled up through the band loop. This forms a small stomach pouch and a narrow outlet to the remaining portion of the stomach. This allows for a quick filling of the small stomach pouch, and a slow emptying of the stomach through the narrow outlet to produce a feeling of satiety.

[0010] U.S. Pat. No. 6,475,136 describes a device for treating heartburn and reflux disease by restricting the amount of food flowing into a stomach or an esophagus, comprising a restriction device (a sphincter or a cuff) that can be adjusted. In one embodiment, the restriction device performs like an artificial sphincter that opens and closes the food passageway in the stomach. In an alternative embodiment, the restriction device comprises an adjustable cuff, a clamp, or a roller to bend or rotate the esophagus or stomach to close or almost close the junction between the stomach and esophagus.

[0011] U.S. Pat. No. 4,246,893 describes a device and method for treating obesity by compressing the stomach and reducing its capacity using a single adjustable distensible device (e.g., a balloon) whose volume can be adjusted from an external port.

[0012] U.S. Pat. No. 5,993,473 and WO 99/25418 describe a device and surgical method for treating obesity by decreasing the volume of the stomach by using a single expandable device placed inside the stomach cavity.

[0013] U.S. Pat. No. 4,694,827 describes a device and method for controlling obesity by deterring ingestion of food using a single balloon that is placed inside the stomach.

[0014] U.S. Publication No. 2002/0188354 describes a device for treating obesity by inserting an hourglass-shaped device into the junction between the stomach and the small bowel, which delays gastric emptying of food.

[0015] U.S. Pat. No. 6,511,490 describes a device for the treatment of morbid obesity by restricting food passage in the stomach by placing an inflatable band around the stomach to create a pouch with a small opening adjacent to the esophagus. The inflatable band is secured and then inflated until the appropriate sized opening is achieved.

DISCLOSURE OF INVENTION

[0016] We have discovered an apparatus and method for effectively treating morbid obesity in mammals, while minimizing the health risks associated with traditional surgery. The device reduces the gastric volume of the stomach and induces early satiety. The "gastric reduction assembly" comprises at least two or more expandable devices (e.g., balloons), each able to be independently inflated and adjusted from an external port. Each expandable device can be filled with a fluid (e.g., CO_2, isotonic dextrose solution, isotonic saline solution, etc.) using a filling tube (e.g., a catheter), which can be easily accessed externally. In a preferred embodiment, the gastric reduction assembly is inserted percutaneously through the antero-lateral abdominal wall, and placed at a location exterior to the stomach body, avoiding an abdominal incision. Laparoscopic guidance, optionally, may be used to assist in placing the gastric reduction assembly near the stomach body. Once positioned near the stomach body, the gastric reduction assembly can be inflated to compress the volume of the stomach and effectively limit food intake. The gastric reduction assembly, with multiple expandable devices, minimizes the potential for post-implantation movement. The expandable devices have a size and shape to complement each other, such that they form a barrier when inflated that minimizes post implantation movement.

[0017] To further minimize inferior migration, a subcutaneous anchor (e.g., a balloon or ring placed within the fatty layer between the skin and the abdominal wall), may be attached to the filling tubes to anchor the expandable devices to the abdominal wall. In addition, each expandable device may use an intragastric anchor (e.g., a collapsible fixation disc) to anchor the expandable device against the stomach body.

Brief Description of the Drawings

[0018] Fig. 1 illustrates a perspective view of one embodiment of the gastric reduction assembly, implanted in the peritoneal cavity around the stomach.

[0019] Fig. 2 illustrates a front view of one embodiment of the gastric reduction assembly which has three expandable devices: two spherical-shaped and one crescent-shaped.

[0020] The invention provides a reliable, inexpensive method for treating obesity in mammals by reducing the volume of the stomach without abdominal surgery, thus reducing postoperative surgical complications. The gastric reduction assembly can provide either an intraperitoneal or an extraperitoneal method to compress the stomach. The placement depends on the surgeon's preference, and the physical condition and body habitus of the patient. In the intraperitoneal cavity, expandable devices can be placed either at a pregastric location (i.e., either anterior or anterolateral to the stomach) or a retrogastric location (i.e., either posterior or posterolateral to the stomach), or both. In the extraperitoneal cavity, the expandable devices can be placed in any of the anatomical compartments, spaces, or layers of the abdominal wall. Candidates for this minimally invasive procedure include patients with a BMI greater than 40, or patients with a BMI less than 40 and a debilitating disease related to the obesity such as diabetes, hypertension, and respiratory insufficiency.

MODES FOR CARRYING OUT THE INVENTION

[0021] The basic design comprises a gastric reduction assembly having at least two or more expandable devices (e.g., balloons), each able to be adjusted and independently inflated. Each device can be inflated with a fluid (e.g., CO_2, isotonic dextrose solution, isotonic saline solution, etc.) using a filling tube. The filling tube is accessed externally by way of an access

device. To inflate each expandable device, the inlet of each filling tube is attached to a corresponding port, and fluid is injected into the inlet via a carrier (e.g., a hypodermic syringe). Fluid flows through the filling tube into each expandable device. Alternatively, fluid can be removed by reversing the process. The filling tubes may be locked together inside a single catheter or other large tubing such that only one tube crosses the abdominal wall to the access port.

[0022] In a preferred embodiment, compression of the stomach is achieved using two or more spherical-shaped expandable devices to form a compressive barrier that reduces the volume of the stomach and minimizes post-implantation movement. Optionally, at least one crescent-shaped expandable device may be used to support the spherical-shaped expandable devices. The shape of the barrier formed by the multiple expandable devices may be adjusted to complement that of surrounding tissues and organs of the patient by changing the volume of the devices.

[0023] To further minimize post-implantation movement, a subcutaneous anchor may be used to help anchor the expandable devices to the abdominal wall. In one embodiment, the subcutaneous anchor is a balloon-like device adapted to circumscribe the filling tubes subcutaneously or below the abdominal wall, at the muscular layer level. The volume of the subcutaneous anchor is adjusted by adding fluid. Alternatively, a ring lock may be placed around each filling tube at the muscular layer. In another embodiment, the expandable devices may be anchored to the stomach using an anchor e.g., a collapsible, fixation disc placed inside the stomach. One method of placement is to pass the intragastric anchor through a separate tube that crosses the expandable device and ends inside the stomach cavity. The tube can be accessed externally.

[0024] The expandable devices can be implanted by passing through the skin and across the anterior abdominal wall via a larger tube to a predetermined implantation site. The expandable devices remain at the site, attached to filling tubes that can be accessed externally through a small single access port.

[0025] The gastric reduction assembly has several advantages. First, the potential for incisional hernia and wound infections is substantially reduced, since no surgical incision of the abdominal wall is needed. The expandable devices are inserted through the skin and across the

anterior abdominal wall via a small puncture. The access device for refilling or deflating the expandable devices is placed in the fatty layers of the abdomen, between the skin and the anterior abdominal muscles. Second, post-implantation movement is substantially reduced, almost eliminating a need to re-orient the expandable devices following implantation. Third, modifications (e.g., inflation, deflation, reorientation, or removal) may easily be done without surgery.

[0026] Fig. 1 illustrates a perspective view of one embodiment of the gastric reduction assembly **2**, in accordance with the present invention. In this embodiment, the device comprises an access device **6**, a subcutaneous anchor **8**, and at least two or more expandable devices **4**, each having an intragastric anchor **10** and a filling tube **12**. Multiple expandable devices **4** are sized and shaped to complement each other such that when inflated, they cluster to form a compressive barrier capable of reducing the stomach volume and minimizing post-implantation movement. To adjustably inflate the expandable devices **4** in the peritoneal cavity, fluid is injected into each filling tube **12** of each expandable device **4** via the access device **6**.

[0027] As shown in Fig. 1, gastric reduction assembly **2** comprises three spherical-shaped expandable devices **4** (e.g., balloons) placed at a pregastric location. Alternatively, gastric reduction assembly **2** may comprise another number of expandable devices **4** (e.g., two, four, five, six, etc.). Optionally, at least one crescent-shaped expandable device **13** may be used, as shown in Fig. 2. This enhances the compressive barrier by forming a carrier ridge to support spherical-shaped expandable devices **4**. Expandable devices **4** can be made of any durable, distensible biocompatible material, such as rubber, latex, or polyurethane elastomer.

[0028] As shown in Fig. 1, each filling tube **12** has an inlet at the access device **6** and an outlet to the interior of each expandable device **4** to allow for inflation with fluid. In an alternative embodiment, a single filling tube **12** that has an inlet and outlet (not shown) for each expandable device **4** may be used. Filling tubes **12** should be made of a durable, flexible, biocompatible material, such as **TYGON ®** tubing, polyurethane, or other plastics.

[0029] As shown in Fig. 1, subcutaneous anchor **8** is a distensible balloon-like device that circumscribes filling tubes **12** within the fatty layer between the skin and abdominal wall or at a subperitoneal (i.e., below the abdominal wall) region to anchor the expandable devices **4** to the abdominal wall. The balloon-like device is inflated via its own filling tube **14**. Alternatively,

subcutaneous anchor **8** can be a ring lock (not shown) that joins all filling tubes **12**. When the ring lock is placed around filling tubes **12** and advanced towards the abdominal wall, it forms an anchor against the muscular layer of the abdominal wall. Subcutaneous anchor **8** should be made of a durable, distensible biocompatible material, such as rubber, latex, or polyurethane elastomer.

[0030] As shown in Fig. 1, intragastric anchor **10** is a collapsible, fixation disc which can be inserted through the stomach wall via tube **12** with a second channel **16** that extends through each expandable device **4**. The disc, once opened in the stomach, anchors expandable device **4** against the stomach. Once intragastric anchor **10** is positioned within the stomach and unfolds, an attached suture may be pulled to form a snug fit between the exterior surface of the stomach body and expandable devices **4**. The size and shape of intragastric anchor **10** is chosen to complement the inner surface of the stomach, and to provide a sufficient surface area (when unfolded) to prevent intragastric anchor **10** from dislodging from the stomach when tension is applied. Intragastric anchor **10** should be made of a biocompatible material capable of shape memory, e.g., nitinol coated with polytetrafluoroethylene.

[0031] An access device **6** comprises ports (not shown) to filling tubes **12**. The size and shape of access device **6** is adapted to allow for a tight seal with filling tubes **12** and a fluid carrier (e.g., a hypodermic syringe). The number of ports is determined by the number of tubes (**12** and **14**) that need to be accessed from the outside.

[0032] A preferred method of implanting the gastric reduction assembly is to go though the skin with a minimally invasive puncture. For example, a nasogastric tube (Bard, Covington, Georgia) is inserted into the stomach. The stomach is then inflated to better visualize it under fluoroscopy so that the proper location for an access site through the skin can be determined. The access site should be below the rib cage, near the gastric chamber. Once the access site is determined, a micropuncture needle (e.g., 22 g; Cook, Inc., Bloomington, Indiana) is inserted into the peritoneal cavity immediately in front of the anterior gastric wall. A microwire (e.g., 0.018 in; Cook, Inc., Bloomington, Indiana) is passed through the needle under fluoroscopic guidance and into the peritoneal cavity. Once the microwire reaches the peritoneal cavity, the micropuncture needle is removed over the wire.

[0033] An access sheath (e.g., 6 French introducer; Cook, Inc., Bloomington, Indiana), a hollow tube that fits through the skin to form a temporary pathway to the peritoneal cavity, is

then inserted over the microwire. The microwire is then removed, leaving the access sheath in place. A guidewire (e.g., 0.035 in stiff regular or hydrophilic; Boston Scientific, Natick, Massachusetts.) is then inserted through the access sheath to provide additional support. The opening in the abdominal wall is progressively dilated with dilators (Cook, Inc. Bloomington, Indiana) from 6-14 French. When the opening is sufficiently large, a larger access sheath (e.g., 14 Fr peel-away sheath; Cook, Inc. Bloomington, Indiana) is placed over the 0.035 in stiff guidewire, and the dilator and guidewire are removed. Air is then evacuated from the stomach through the nasogastric tube to provide space for the gastric compression assembly **2**.

[0034] Introducer tubes (e.g., catheters) containing expandable devices **4** (e.g., balloons) attached to filling tubes **12** are inserted through the access sheath to a predetermined position near the stomach. Expandable devices **4** are released from the introducer tubes. The expandable devices **4** are then partially inflated sequentially near the stomach using a syringe to introduce fluid (e.g., CO2, isotonic saline solution, or isotonic dextrose solution) to the expandable devices **4** through the filling tubes **12**. Introducer tubes are slowly withdrawn, and each filling tube **12** is pulled until each partially inflated expandable device **4** contacts the abdominal wall. The access sheath is then removed, and a subcutaneous anchor **8** (e.g., a balloon or ring lock) is placed within the fatty layer between the skin and abdominal wall or the subperitoneal region (i.e., below the abdominal wall) to anchor expandable devices **4**. Expandable devices **4** are then inflated to a volume sufficient to compress the stomach, and filling tubes **12** cut to an appropriate length. The inlets to filling tubes **12** are then attached to the ports of access device **6**, and access device **6** is placed within the fatty layer between the skin and abdominal wall. The skin is then closed with sutures.

[0035] In an alternative embodiment, each expandable device **4** is individually introduced to a preselected stomach compression site near the stomach and then anchored to the stomach, as described below. In this embodiment, filling tube **12** to each expandable device **4** has at least two channels. Filing tube **12** is positioned to pass through expandable device **4** and abut the side of expandable device **4** that is near the stomach. One channel of filling tube **12** has an opening that allows fluid to flow into expandable device **4** to inflate the device. The second channel of filling tube **12** passes intact through expandable device **4** to the wall near the stomach. This channel allows an intragastric anchor **10** to be placed inside the stomach to help anchor

expandable device **4** as described below. Initially, a needle (e.g., an 18-gauge needle; Cook, Inc. Bloomington, Indiana) is passed through the access sheath to puncture the stomach wall. A contrast medium (e.g. gastrograffin) is then injected into the stomach to determine the needle's location. Once the location is determined, a suture **22** is attached to intragastric anchor **10**, and the collapsed anchor is advanced through the needle into the stomach in a collapsed form using a stiff guidewire (e.g., 0.035 cm guidewire; Boston Scientific Corp, Natick, Massachusetts.). Upon exiting the needle outlet within the stomach, intragastric anchor **10** resumes its disc-shaped configuration. Intragastric anchor **10** can be covered with a biocompatible material (e.g., **GORTEX ®**, **DACRON ®**, polyethylene or silicone) to help seal the gastric puncture site. The 18-gauge needle is then removed, while the stiff guidewire and suture remain attached to the intragastric anchor **10**. Preferably, suture **22** is attached to the guidewire to allow for withdrawal. This process is repeated for each of the remaining expandable devices **4**. The stiff guidewire is then passed through the second channel of filling tube **12** for each expandable device **4**. Expandable devices **4** are then positioned at preselected stomach compression sites as described above. After verifying the compressive effects of each expandable device **4** on the gastric volume of the stomach, the stiff guidewires are disconnected from sutures **22** and removed. Each suture **22** is then pulled back through the second channel of filling tube **12** to anchor the device to the stomach wall. The access sheath is then removed, and filling tubes **12** are cut to an appropriate length. The ends of each suture are pulled through the second channel and attached to access device **6** to anchor expandable devices **4**. Expandable devices **4** can then be inflated or deflated through access device **6**, as necessary. Access device **6** is then placed within the fatty layer between the skin and the abdominal wall, and the skin is closed with sutures.

[0036] Clinical trials will initially involve testing two groups (a test and a control) of pigs weighing more than 50 kg. The gastric reduction assembly will be implanted into the test group. Once the gastric reduction assembly has been implanted, an upper gastrointestinal study ("UGI") will be conducted with barium to check the gastric volume and passage of material through the stomach into the small intestine. The volume of the expandable devices will be adjusted in the test group based on the findings of the UGI. UGIs will be conducted at various intervals to check on the location and volume of the expandable devices. The two groups will be weighed weekly.

After six months, the animals will be euthanized and the position of the gastric reduction assembly evaluated during necropsy. The data will be analyzed for differences in weight loss between the two groups.

[0037] The complete disclosures of all references cited in this specification are hereby incorporated by reference. In the event of an otherwise irreconcilable conflict, however, the present specification shall control.